DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

3/18/97
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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100



cc: HFI-35/FOI Staff
DWA

March 10, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

**Refer to MIN 97-37**

William W. George
President and Chief Executive Officer
Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432-3576

Dear Mr. George:

During an inspection of your firm's Neurological Division located in Minneapolis, MN, on February 4-6, 11, 1997, our Investigator verified that your firm continues to manufacturer Class III implantable drug infusion pumps (Synchromed Programmable Pumps).

Implantable drug infusion pumps are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. The product hold process and procedures are inadequate to preclude inadvertent release of product that does not meet its performance specifications (21 CFR Part 820.150).

2. Failure to qualify/validate the leak test step for the Syncromed Bulkhead part #107090 Rev T [21 CFR Part 820.100 (a)(2)].

3. Regarding the receiving procedure for bulkhead P/N 107090 Rev T:

   A. Failure to verify the thickness of the part at the intersection of the bacterial filter countersink and the septum wall [21 CFR Part 820.80(a)];

   B. Lack of a requirement of visual inspection of the part for cracks, folds, and other anomalies [21 CFR Part 820.80(a)].

These deficiencies resulted in your firm's release of non-conforming products, some of which were implanted into patients.

Our concern over your release of products that should have been placed on hold and withheld from distribution is heightened when considered in light of the release/distribution in April 1995 of Model 7219D Jewel implantable defibrillators from Medtronic's Finished Goods Distribution Center in Moundsview, MN, prior to FDA's PMA approval. As the Moundsview distribution center ships products from multiple Medtronic divisions, it is important that this problem be addressed from a systematic perspective as well as within the Neurological Division.

It should be noted that your firm's Neurological Division has initiated three recalls/safety alerts within the past year:

(1) Medtronic Synchromed Programmable Pumps (recall #Z-152/156-7)--open electrical circuits;

(2) Medtronic Synchromed Programmable Pumps (recall #Z-1035-6)--missing welds;

(3) Medtronic InDura Intraspinal Catheters (recall #Z-223-7)--lack of radio-opaque component.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president and CEO, the most responsible individual at Medtronic, Inc., it is ultimately your responsibility to ensure that devices manufactured at and distributed from your facilities are in compliance with each requirement of the Act and regulations.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for pre-market approval (PMA's) or export approval requests will be approved and no pre-market notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured at your facility until the violations have been corrected.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Thank you for the letter dated February 21, 1997, from Patrick J. Eichers in response to our February 11, 1997, FDA-483, Inspectional Observations form that was issued to your Neurological Division. Your responses to the concerns referenced in the FDA-483 are noted and are being made part of the official file.

The corrective actions that you are taking are appropriate for addressing the concerns raised during the February 1997 inspection. During the next inspection

we will assess the effectiveness of the implementation of the corrective measures that you reference in your letter.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to ensure that similar violations will not recur. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612)334-4100 ext. 156.

Sincerely yours,

John Feldman
Director
Minneapolis District

HEM/ccl

Enclosures: FDA-483, 2/11/97

xc: Patrick J. Eichers
DDB Quality Systems Manager
Medtronic, Inc.
Neurological Division
800-53rd Avenue N.E.
Minneapolis, MN 55440-9087